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EXAMINER				
PURDY, KYLE A				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary**Application No.**

09/754,010

Applicant(s)

DILLON, MARK E.

Examiner

K Purdy

Art Unit

1611

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 July 2012.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 5) ☒ Claim(s) 34-36, 38, 39 and 41-54 is/are pending in the application.
- 5a) Of the above claim(s) 46-54 is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 34-36, 38, 39 and 41-45 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
- Paper No(s)/Mail date ____
- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date ____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____

DETAILED ACTION

Status of Application

1. The Examiner acknowledges receipt of the arguments and amendments filed on 7/26/2012.
2. Claim 34 has been amended.
3. Claims 34-36, 38, 39 and 41-45 are presented for examination on the merits. The following rejections are made.

Response to Applicants' Arguments

4. Applicants arguments filed 7/26/2012 regarding the rejection of claims 44 made by the Examiner under 35 USC 103(a) over Freeman et al. (US 5681579) in view of Lorenz et al. (US 5258421), evidenced by US 4832009 have been fully considered. This rejection has been withdrawn because neither reference teaches the claimed thickness of the bottom outermost layer (foam layer).

5. Applicants arguments filed 7/26/2012 regarding the rejection of claims 34-36, 38, 39, 41-43 and 45 made by the Examiner under 35 USC 103(a) over Freeman et al. (US 5681579) in view of Lorenz et al. (US 5258421), evidenced by US 4832009 have been fully considered but they are not found persuasive and is **MAINTAINED** for the reasons of record in the office action mailed on 7/21/2011.

6. In regards to the 103(a) rejection, Applicant asserts the following:

A) none of the cited references teaches or suggests, either alone or in combination, Applicants dual-purpose wound dressing wound dressing having both a first wound contacting side and a second wound contacting side. For example, Freeman states that their invention

provides for the rapid uptake of wound exudate away from the wound, while still providing a moist, occlusive, hydrocolloid environment for wound healing. Clearly, Freeman does not disclose a dual-purpose wound dressing having two different wound contacting outer surfaces having two different wound healing characteristics; and

B) typically, according to Freeman, an adhesive layer is applied to the outer face of the support layer, or to the inner surface of an overhanging portion of the occlusive backing layer, for adhering the dressing to the skin of a patient.

7. In response to A, Applicants argument is not persuasive. First, it is noted that nowhere in the claims is the wound healing characteristics defined. Thus, the characteristics could be anything, broadly speaking, relating to wound healing. Freeman teaches that their outer polymeric support layer provides a pathway for uptake of body fluids whereas their outer occlusive layer blocks the exit of wound exudate or entry of foreign, possibly contaminated, fluids. Both of these sides would possess distinct wound healing characteristics if one was so motivated to provide either side to the surface of the wound. Second, Applicant is arguing an intended use for their product. How the two sides of the product are use are immaterial to the product itself. What defines the claim is the structure of the product being claimed, not the method by which the product is to be used. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

8. In response to B, Applicants argument is not persuasive. Claim 34 reads, "...a bottom outermost layer forming the first wound contacting side of the composite structure, the bottom

outermost layer being a membrane layer, the membrane layer having an outer surface, the outer surface of the membrane layer forming the wound contacting surface of the first wound contacting side of the composite structure....” Freeman provides several embodiments for their wound dressing which are exemplified by Figure 1 and Figure 2. Figure 1 provides the polymeric support layer as an island on the occlusive layer. The adhesive provided on the interior occlusive overhang secures the bandage to the skin. Figure 2 is a bit different wherein the occlusive and polymeric support layers are of the same length and adhesive is provided to a portion (e.g. perimeter) of the polymeric layer so that the bandage could secure to the skin (see column 6, lines 1-10). Both of these embodiments obviate Applicants claimed structure as there is nothing in the claims that precludes a bottom of the occlusive layer from being coated with an adhesive layer or a portion of the outermost layer from possessing an adhesive material so long as a portion of said outermost layer remains exposed or possesses an ‘outer surface’.

Maintained Rejections, of Record (claims 34-36, 38-43 and 45) and New Rejection (claims 41 and 44)

Claim Rejections - 35 USC § 112

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. **Claim 41 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.**

11. In particular, claim 41 recites, ‘the top outermost layer being substantially opaque’ and the ‘bottom outermost layer being substantially transparent’. It is unclear what ‘substantially

opaque' and 'substantially transparent' encompasses. There is no clear standard for measuring the degree intended by the claim. What would not qualify as 'substantially transparent' and what would qualify as 'substantially opaque'? Would something slightly opaque read on the claims or not? The use of the term 'substantially' does not give one of skill in the art sufficient clarity so as to understand the invention.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claims 34-36, 38, 39, 41-43 and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Freeman et al. (US 5681579; of record) in view of Lorenz et al. (US 5258421; of record), evidenced by US 4832009 (of record) and Applicants specification.

14. Freeman discloses a polymeric support wound dressing (see abstract). Figure 1 discloses the occlusive layer (11) (second layer) bonded by adhesives (13) means to a hydrocolloid containing polymeric layer (12) (first layer).



The occlusive layer 11 has an upper or outer surface 14, which is open to the atmosphere and an inner surface 13 which faces the skin. The occlusive layer is preferably a polyurethane foam (see

column 4, lines 30-31). The adhesive layer may, for example, extend across the entire under surface 13 of the occlusive layer or only a portion of it (see Fig 1; see column 4, lines 65-68). The polymeric support layer 12 is any polymeric material useful in medical settings and is in the form of a web, net, perforated film or perforated layer. The polymeric support layer 12 contains a hydrocolloid blended with the polymeric material wherein the polymeric material is polyurethane (see column 1, lines 10-20). It should be noted that a membrane is defined as a "thin, soft pliable sheet or layer"; thus Freeman's polymeric support reads on instantly claimed "membrane layer". The polymeric film is to be perforated (fenestrated; see instant claim 42) so as to provide a fluid path for the wounds (see column 5, lines 30-35). Further, the polymeric support layer may range from 0.5-1.5 mils (about 10 microns to about 40 microns; 1 mil = 0.0254 mm - math not shown) (see column 9, lines 35-40). The adhesive layer is made of various substances including elastomeric silicone rubber (see column 6, line 31).

15. Freeman does not teach the bottom outermost layer (polymeric support layer) as comprising a silicone-containing compound, specifically silicone-polytetrafluoroethylene IPN membrane layer. Freeman fails to suggest the inclusion of a pigment.

16. Lorenz teaches a hydrophilic gel dressing (see abstract). Lorenz teaches coating a gel layer on a backing substrate that provides liquid barrier properties and may be a polymer film such as polyurethane. The polymer film may also be silicone-polytetrafluoroethylene IPN membrane (see column 1, lines 60-65). Lorenz teaches silicone-polytetrafluoroethylene has particular utility in wound dressing because it retains moisture and excess exudate is absorbed to promote healing (see column 5, lines 50-68). When the backing substrate is of the instant silicone-polytetrafluoroethylene, the structure is also useful as a burn blanket (see 5, lines 30-33

and column 6, lines 28-30). Thus, one would have been motivated to use the IPN polymer of Lorenz in place of the suggested polymeric support material of Freeman as it's taught that IPN has beneficial barrier properties such as improving wound healing by keeping the moisture in, preventing bacteria from entering the wound and absorbing the excess exudates. Therefore, a skilled artisan would have been motivated to utilize the instant polymer film (IPN) in the wound dressing over Freeman's polyurethane film for the advantages taught by Lorenz, i.e. desire to provide a structure that also promoted healing by preventing re-infection, by preventing bacteria from entering the wound site, etc.. Additionally, the backing substrate may be covered by a silicone-coated release-liner. Various conventional additives such as pigments and dyes in the gels are contemplated (see column 4, lines 49-55).

17. With regard to claim 41, it is noted that the polymeric film layer of silicone-polytetrafluoroethylene IPN are implicitly translucent unless a pigment is added and the polyurethane foam is opaque. US '009 and Applicants own specification substantiates the Examiners position that the silicone-polytetrafluoroethylene IPN are transparent and polyurethane foams are opaque. Note column 1, lines 55-60 of US '009 and Example 2 of Applicants own specification. Thus, the combination of Freeman and Lorenz would produce a product having the properties being claimed. With regard to the addition of pigment to the adhesive layer, it is considered *prima facie* obvious to add a pigment to any layer to distinguish it from the other layers. Aesthetic design changes do not impart patentable significance with regard to the mechanism in which the wound article functions. See MPEP 2144.04 I.

18. With respect to claim 45, it would be expected, absent evidence otherwise, that the combination of references would result in a bandage having a thickness sufficient to impart resistance to roll-up, slippage and wrinklage.

19. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the teaching of Freeman with the teaching of Lorenz such that the polymeric material in the membrane layer of Freeman is replaced by the silicone-polytetrafluoroethylene IPN polymer taught as by Lorenz with a reasonable expectation for success in improving the wound healing characteristics of the wound dressing of Freeman. Therefore, the invention as a whole is *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in absence of evidence to the contrary.

20. Claim 44 is rejected under 35 U.S.C. 103(a) as being unpatentable over Freeman et al. (US 5681579; of record) in view of Lorenz et al. (US 5258421; of record), evidenced by US 4832009 (of record) and Applicants specification as applied to claims 34-36, 38, 39, 41-43 and 45 above, and further in view of Nowakowski (US 3949742; published 4/13/1976).

21. Freeman and Lorenz fails to teach the foam layer as having a thickness of about 50 microns.

22. Nowakowski is directed to medical dressings comprising a foam layer and a non-porous segmented polyurethane thin layer. The foam layer is present so as to absorb bodily fluids lost due to wounds. The foam layer is to have a thickness about 8-60 mils (see column 2, lines 1-5) which corresponds to a thickness of 200 microns to about 1500 microns (math not shown). It would have been obvious to modify the foam thickness of Freeman to have a thickness of about

1500 microns, as taught by Nowakowski, with a reasonable expectation for success in absorbing wound exudate.

23. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Freeman and Lorenz with the teaching of Nowakowski such that the foam layer would have a thickness of about 1500 microns with a reasonable expectation for success in absorbing wound exudate. Therefore, the invention as a whole is *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in absence of evidence to the contrary.

Conclusion

24. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kyle A. Purdy whose telephone number is 571-270-3504. The examiner can normally be reached from 9AM to 5PM.

25. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Daniel Sullivan, can be reached on 571-272-0779. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

26. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/K Purdy/
Examiner, Art Unit 1611

